UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

JANE DOE,)	
	PLAINTIFF,)	NO. 1:24-CV-966
-against-)	JURY TRIAL DEMANDED
SACHIN SHRIDHARANI, M.D.;)	
LUXURGERY, LLC; SIENTRA, INC.;)	
ADVARRA, INC.;)	

DEFENDANTS.

COMPLAINT

Plaintiff Jane Doe ("Plaintiff"), by and through her attorneys, Fegan Scott LLC, for her Complaint against Sachin Shridharani, M.D. ("Dr. Shridharani"), Luxurgery, LLC ("Luxurgery"), Sientra, Inc. ("Sientra"), and Advarra, Inc. ("Advarra") (collectively, Defendants), alleges as follows:

I. NATURE OF THE ACTION

- 1. Patient–physician confidentiality is the cornerstone of medical ethics, which fosters trust.¹ "Without trust, how could a physician expect patients to reveal the full extent of their medically relevant history, expose themselves to the physical exam, or act on recommendations for tests or treatments?"²
- 2 Dr. Shridharani and the practice he founded, Luxurgery, violated this trust by videotaping Jane Doe's breast augmentation surgery, which was conducted as part of a Sientrasponsored research study, without her written consent. Luxurgery then posted the video, or

¹ Nasrin Nejadsarvari, Ali Ebrahimi, Azin Ebrahimi, and Haleh Hashem-Zade, "Medical Ethics in Plastic Surgery: A Mini Review," World J Plast Surg. 2016 Sep; 5(3): 207–212, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5109381/ (last accessed Jan. 25, 2024).

² Susan Dorr Goold, MD, MHSA, MA, Trust, Distrust and Trustworthiness: Lessons from the Field, 17 J. GEN. INTERNAL MED. 79, 79–81 (2002) (citations omitted).

excerpts thereof, displaying Jane Doe's naked breasts to its public social media outlets to promote Dr. Shridharani and his practice.

- 3. As soon as Jane Doe became aware of the social media posts, she immediately demanded that Dr. Shridharani and Luxurgery remove the video from publication. Dr. Shridharani apologized, and Luxurgery removed the video from social media.
- 4. But then several months later, Luxurgery posted the video *a second time* to social media, promoting Dr. Shridharani and his plastic surgery practice.
- 5. Jane Doe again complained to Luxurgery and demanded that the video be removed from social media. She also notified Advarra, which is the institutional review board retained by Sientra "to help protect the rights of research subjects." Luxurgery removed the video, and Advarra claimed that it would require Luxurgery to implement proper controls (but apparently failed to do so).
- 6. Subsequently, despite Jane Doe's objections made to Dr. Shridharani and his practice, and clear instructions that they were not allowed to make any use of the video (for which they did not have consent to film in the first place), Dr. Shridharani and Luxurgery posted an excerpt of the video, clearly displaying Jane Doe's naked breast, to social media *a third time*.
- 7. Jane Doe has suffered extreme emotional distress as a result of being videotaped while unconscious without her consent and having the video posted publicly on social media for the world to see her naked breasts *on three different occasions over her strenuous objections and report to Advarra*.
 - 8. Jane Doe seeks compensatory and exemplary damages and brings this action

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³ Informed Consent Form and Authorization to Use and Disclose Protected Health Information, at 7.

against Dr. Shridharani and Luxurgery for violations of New York Civil Rights Law §§ 50, 51 (Invasion of Right of Privacy), New York Civil Rights Law §§ 52-B (Unlawful Dissemination or Publication of an Intimate Image), and breach of physician-patient confidentiality (NY CPLR § 4503). She also brings claims against Luxurgery for negligent retention and supervision; Sientra and Advarra for negligent supervision and direction; and all Defendants for infliction of emotional distress.

II. JURISDICTION AND VENUE

- 9. This Court has subject matter jurisdiction because Plaintiff is a resident of a different state than Defendants, such that the Plaintiff is not domiciled in the same state as any Defendant, and the amount in controversy exceeds \$75,000.00.
- 10. This Court has personal jurisdiction over Dr. Shridharani because Defendant resides in New York and/or conducts or, at relevant times conducted, activities in the State of New York that give rise to the claims asserted herein.
- 11. This Court has personal jurisdiction over Luxurgery because Defendant conducts or, at relevant times conducted, activities in the State of New York that give rise to the claims asserted herein.
- 12. This Court has personal jurisdiction over Sientra because Sientra, in person or through an agent, transacts business within the state, and Plaintiff's claims arise from that business activity. Further, the exercise of personal jurisdiction comports with due process where Sientra has certain minimum contacts with the forum state such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.
- 13. This Court has personal jurisdiction over Advarra because Advarra, in person or through an agent, transacts business within the state, and Plaintiff's claims arise from that business

activity. Further, the exercise of personal jurisdiction comports with due process where Advarra has certain minimum contacts with the forum state such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.

14. Venue for this action is proper in the Southern District of New York in that Defendant Luxurgery resides in this District and all or the majority of the events and/or omissions giving rise to the claims asserted herein occurred here.

III. PARTIES

- 15. Plaintiff Jane Doe is a resident of Broward County, Florida and a citizen of the United States.
- 16. Defendant Sachin Shridharani, M.D. is, on information and belief, a resident of New York County, New York. Dr. Shridharani is the founder of Defendant Luxurgery, LLC and performs surgery at 880 Fifth Avenue, 1-B,C,D, New York, NY 10021.
- 17. Defendant Luxurgery, LLC is a Missouri limited liability corporation with its principal place of business located at 880 Fifth Avenue, 1-B,C,D, New York, NY 10021.
- 18. Defendant Sientra, Inc. is a Delaware corporation with its principal place of business located at 3333 Michelson Drive, Suite 650, Irvine, CA 92612. Sientra's registered agent in New York is Registered Agent Solutions, Inc., 99 Washington Avenue, Suite 1008, Albany, NY 12260.
- 19. Defendant Advarra, Inc. is a New York corporation with its principal place of business located at 6100 Merriweather Dr., Suite 600, Columbia, MD 21044. Advarra's registered agent in New York is CT Corporation System, 28 Liberty St., New York, NY 10005.

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IV. FACTS

- A. While agreeing to take part in a research study involving breast augmentation, Jane Doe requested orally and in writing that any photographs taken of her be used solely for research purposes.
- 20. Jane Doe consented to take part in the Sientra, Inc. "Prospective Study on Fat Retention when using the AuraGen 1-2-3TM with AuraClensTM System in Processing of Lipoaspirate for Autologous Fat Grafting to the Breast" ("Study").
- 21. Jane Doe signed the Informed Consent Form and Authorization to Use and Disclose Protected Health Information on March 6, 2023 ("Informed Consent Form"), a redacted copy of which is attached as Ex. A.
- 22. The Informed Consent Form identifies Sientra as the Sponsor, Dr. Shridharani as the Principal Investigator, Luxurgery as the location for the surgery, and Advarra as the Study Subject Adviser.
- 23. The stated purpose of the study is to collect data on the amount of fat that is retained in a subject's body over time after surgery with the AuraGen 123 system, a medical device. In Jane Doe's case, the medical device was used during breast augmentation surgery in which fat cells and tissue grafted from her stomach or thighs was injected into her breast.
- 24. According to the American Academy of Plastic Surgeons, breast augmentation surgery is a "deeply personal procedure," which Jane Doe intended to keep highly private.
- 25. The Informed Consent Form provides that photographs and 3D imaging might be taken of her breasts for dimensional measurement, that reasonable measures would be taken to ensure that identifying information would not be included in any photographs, and that the photographs would only be shared with the Investigator, study site personnel, the study sponsor,

⁴ https://www.plasticsurgery.org/cosmetic-procedures/breast-augmentation/candidates (last accessed Jan. 25, 2024).

and sponsor authorized representatives for research purposes.

- 26. In the Informed Consent Form, Jane Doe expressly withheld consent to the use of any photographs for marketing purposes.
- 27. The Informed Consent Form did not disclose that any video recordings of Jane Doe would be taken while she was unconscious during surgery.
 - B. Because Jane Doe's breast augmentation surgery was deeply personal and confidential to her, she confirmed and received assurances in writing from Luxurgery that any photographs taken of her would be used only for research purposes.
- 28. Even though she had the Informed Consent, which limited the use of any photographs to research purposes, Jane Doe remained highly concerned about how any pictures of her naked body could be used.
- 29. Because of her concern, Jane Doe called Luxurgery by telephone on March 13, 2023 to make sure that any pictures taken of her would not be publicly shared. She spoke with Christina, whose last name, on information and belief, is Uong and who is a Surgical Assistant at the practice.⁵
- 30. Christina told Jane Doe the pictures could only be used for research purposes. Christina then followed up that same day with an email, writing to Jane Doe that she spoke with the research team and that any photographs taken of Jane Doe could "only be published in medical journals for other plastic surgeons/ healthcare professionals but not for the general public. In addition, identifying features will be edited out as well such as face and tattoos."
- 31. Based on the Informed Consent Form and the assurances provided by Christina, Jane Doe went forward with the surgery, which took place on March 22, 2023.

⁵ https://www.linkedin.com/in/christina-uong/ (last accessed Jan. 28, 2024).

- During the pre-operative preparations, Jane Doe met with Dr. Shridharani and three other people from Luxurgery.
- 33. During an examination, patients should be draped except for the area being examined. Patients should never be required to lie or stand in an exam room while completely naked.
- 34. However, during the pre-operative preparations, Dr. Shridharani required Jane Doe to strip completely naked.
- 35. Dr. Shridharani and his team took photographs of Jane Doe while she was completely naked. They subsequently had her put her underwear on, and then took additional pictures.
- 36. Jane Doe understood that these pictures would be used solely for research purposes and/or be solely used to monitor her progress before and after surgery.
- 37. During this meeting, Dr. Shridharani placed markings on Jane Doe's body for him to follow during the surgery.
- 38. While he was making the markings and Jane Doe was naked, Dr. Shridharani requested multiple times that Jane Doe allow him to videotape her. She repeatedly said that she did not want to be videotaped and that she didn't want her surgery out in the public domain.
- 39. Dr. Shridharani encouraged Jane Doe to allow him to record the surgery, telling her that some people liked to watch their surgery later. Jane Doe told him that she did not want to watch the surgery and did not want her surgery to be put on social media. She told him and his team that she did not want her body on video or on social media.
- 40. Based on this conversation, Jane Doe did not have any understanding that Dr. Shridharani and Luxurgery nonetheless intended to record a video of the surgery, much less to

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record a video of the surgery for marketing purposes.

- 41. On March 23, 2023, Jane Doe went for a follow up appointment at Luxurgery (necessary as a result of her surgery) and again confirmed orally that any photographs taken of her body for research purposes would not be publicly shared.
 - 42. Jane Doe was assured that pictures of her would not be publicly shared.
- 43. No one from Luxurgery disclosed to her at this appointment that a video had been taken of her while she was unconscious during surgery nor that such video would be used for marketing purposes.
 - C. For the first time, and without Jane Doe's consent, Dr. Shridharani and Luxurgery posted a video of Jane Doe's surgery, displaying her naked breast and areola on social media.
- 44. Despite the express language of the Informed Consent and Luxurgery's repeated reassurances, on March 24, 2023, Jane Doe saw a video of her unclothed body, including her naked breast and areola, taken during the surgery and posted by Dr. Shridharani and Luxurgery on TikTok and Instagram.
 - 45. The video clearly depicts identifying marks on Jane Doe's body, including a tattoo.
- 46. Jane Doe contacted Luxurgery on March 24, 2023 to complain, and the video was removed from social media.
- 47. The same day, Dr. Shridharani called Jane Doe and apologized, but blamed Jane Doe by claiming that she had consented to the use of the video since she signed up for a research study. Nonetheless, Dr. Shridharani told her that it would not happen again.
- 48. Jane Doe was extremely shocked and distressed. She had carefully completed the Informed Consent Form to make sure that she was not consenting to the use of photographs for marketing purposes. Nowhere on the form was it disclosed that a video recording of her surgery

would be made.

- 49. She had followed up after signing the Informed Consent Form and received written confirmation from Luxurgery that any photographs would only be used for research purposes. And she had expressly declined immediately before the surgery to be videotaped or to have images of her naked body used for marketing or social media purposes.
- 50. Notwithstanding how careful Jane Doe had been to ensure that her surgery would be treated with the utmost confidentiality, Dr. Shridharani and Luxurgery had broken her trust and displayed her naked body on social media.
- 51. As a result, Jane Doe told Luxurgery that she did not feel comfortable participating in further study follow-up given that she did not feel safe because of the violation of her rights and privacy. While she had to return one more time to get her stitches removed, she refused to fully undress and did not consent to any additional pictures being taken.
 - D. For the second time, without Jane Doe's consent and despite their promises not to do it again, Dr. Shridharani and Luxurgery posted the video of Jane Doe's surgery displaying her naked breast and areola on social media.
- 52. On June 16, 2023, Jane Doe again saw the video of her unclothed body, including her breast and areola, taken during her surgery on social media. The video had been posted a second time by Dr. Shridharani and Luxurgery on TikTok and Instagram on June 14, 2023.
- 53. Just as the first time, the video clearly depicts identifying marks on Jane Doe's body, including a tattoo.
- 54. Jane Doe again contacted Luxurgery to complain, and after significant push back by Luxurgery, the social media posts were removed.
 - 55. On June 16, 2023, Jane Doe also sent an email to the Study Subject Advisor,

Advarra, seeking action to ensure that the posting of the videos depicting her intimate body parts on social media would not occur again.

- 56. Jane Doe expected that Advarra would help protect her given that its job was to ensure that the rights of study participants were not violated.
 - 57. Jane Doe wrote to Advarra:

I had recently agreed to be a participant in the Study Reference: Pro00061014 and I am reporting a violation in the study. On March 24th 2023, I saw a video of me in this procedure that was posted by Dr. Sachin M Shridharani on social media. I immediately contacted the office and they removed it. I was shocked, however, to once again find that the video was reposted again on June 14th, 2023 once again without my consent. The video clearly shows my tattoo as well as my areola in plain view. The contract clearly states that all identifying features and marks will be removed and my own marks were clearly not removed on these videos as well as my nude body.

The Investigator medical doctor clearly has broken the contract and I have been harmed both psychologically and emotionally and feel violated and abused by the Investigator. I am demoralized and cannot believe that such an occurrence would happen involving medical research. This has triggered me to the point where I have been feeling suicidal- as I am already in therapy for prior sexual abuse. I am enclosing a letter from my therapist as well. I would like this matter to be promptly addressed. I only consented to a scientific study and not to any marketing wherein my personal marks and identifiers as well as my areola are clearly visible. The Investigator misled me and had reassured me that my images/video would NOT be used for marketing purposes. To this point, the investigator has clearly harmed me for his own financial gain and profit.

- 58. While Advarra confirmed receipt of the email, it largely ignored Jane Doe. For the next two months, Jane Doe regularly followed up with Advarra to find out how it intended to protect her rights.
 - 59. After two months, on August 16, 2023, Advarra simply responded: "After review,

the Board has determined that the site will be required to revise the consent form and change their processes in regard to collecting photographs, videos, and/or audio recordings of patients." Advarra was silent as to how Jane Doe would be protected from the use of pictures and video of her by Dr. Shridharani and Luxurgery for marketing purposes.

- 60. Jane Doe was very upset by Advarra's response and its failure to help protect her.
 - E. For the third time, without Jane Doe's consent and despite their promises not to do it again, Dr. Shridharani and Luxurgery posted the video of Jane Doe's surgery on social media.
- 6l. On January 10, 2024, for the third time, Dr. Shridharani and Luxurgery posted a video on Instagram and TikTok which is comprised of multiple videos of multiple women, including a segment of the video of Jane Doe's surgery.
- 62. Jane Doe saw this video on January 12, 2024, causing her extreme emotional distress.
- 63. The blatant disregard of Dr. Shridharani and Luxurgery to Jane Doe's civil rights is shocking.
- 64. Moreover, Sientra's and Advarra's lack of controls or policies in place to ensure that the video and images were not used the first time much less a third time after the Study Subject Advisor was notified of Dr. Shridharani's breach of the Informed Consent Form reflects a blatant disregard of study participants' rights.
- 65. Finally, as the Study Sponsor, Sientra was responsible for choosing the Principal Investigator and for monitoring Dr. Shridharani, both of which negligently and/or willfully breached the Informed Consent Form or allowed the breach of the Informed Consent Form to occur three times.

F. Plaintiff has been damaged.

- 66. Plaintiff had previously been diagnosed with Chronic Post-Traumatic Stress Disorder as well as Complex Post-Traumatic Stress Disorder, as a result of recurring or long-term traumatic events.
- 67. According to Jane Doe's treating licensed psychotherapist, Jane Doe was making good progress in re-working and alleviating traumatic pain and stress until June 14, 2023 when she saw the video of her posted for the second time on social media.
- 68. According to her psychotherapist, Jane Doe was visibly despondent after viewing the video on social media that revealed her body, because viewing the video caused Jane Doe to experience flashbacks. The video has caused significant damage to Jane Doe's trauma recovery.
- 69. According to her psychotherapist, Jane Doe's estimated global assessment of functioning denoted that she was experiencing suicidal thoughts as a result of the video. Jane Doe's affective and emotional state appeared quite depressed, marked by hopelessness, anxiety, anger, and regression.
- 70. The posting of this video, or excerpts thereof, to social media has caused Jane Doe significant emotional and psychological harm, and at times has overwhelmed her daily functioning.
- 71. Moreover, it has significantly affected her trust in physicians, causing her to forego standard medical care.

V. CAUSES OF ACTION

COUNT I – VIOLATION OF NEW YORK CIVIL RIGHTS LAW §§ 50, 51 (INVASION OF RIGHT OF PRIVACY) (AGAINST DR. SHRIDHARANI AND LUXURGERY)

72. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.

- 73. Plaintiff brings this Count I against Dr. Shridharani and Luxurgery.
- 74. Section 50 of New York Civil Rights Law provides:

A person, firm or corporation that uses for advertising purposes, or for the purposes of trade, the name, portrait or picture of any living person without having first obtained the written consent of such person, or if a minor of his or her parent or guardian, is guilty of a misdemeanor.

N.Y. Civ. Rights Law § 50.

- 75. As described above, Dr. Shridharani and Luxurgery made a video recording of Plaintiff's breast augmentation surgery without her written consent.
- 76. The video recording, which displayed her naked body and identifying marks, was posted by Dr. Shridharani and Luxurgery on social media, including but not limited to Instagram and TikTok, for marketing purposes without Plaintiff's written consent and over her objections on at least three separate occasions.
- 77. Defendants' postings on social media violated Section 50 of New York Civil Rights Law.
 - 78. Section 51 of New York Civil Rights Law provides in pertinent part:

Any person whose name, portrait, picture or voice is used within this state for advertising purposes or for the purposes of trade without the written consent first obtained as above provided may maintain an equitable action in the supreme court of this state against the person, firm or corporation so using his name, portrait, picture or voice, to prevent and restrain the use thereof; and may also sue and recover damages for any injuries sustained by reason of such use and if the defendant shall have knowingly used such person's name, portrait, picture or voice in such manner as is forbidden or declared to be unlawful by section fifty of this article, the jury, in its discretion, may award exemplary damages.

N.Y. Civ. Rights Law § 51.

79. Plaintiff seeks an injunction to restrain Defendants' use of any images or video

recordings of Plaintiff. Plaintiff also seeks compensatory and exemplary damages.

- As a result of Defendants' conduct described herein, Plaintiff has and will continue to suffer personal psychological injuries, including but not limited to great pain of mind and body; severe and permanent emotional distress; physical manifestations of emotional distress; feelings of worthlessness, shamefulness, and embarrassment; losing faith in authority figures; struggling with gainful employment and career advancement; feeling helpless and hopeless; problems with sexual intimacy; relationship problems; trust issues; feeling confused and angry; depression; and anxiety. Plaintiff was prevented from and will continue to be prevented from performing Plaintiff's normal daily activities; has incurred and will continue to incur expenses for psychological treatment, therapy, and counseling; and, on information and belief, has incurred and will continue to incur loss of income and/or loss of earning capacity.
- 81. Plaintiff seeks an injunction to restrain Defendants' use of any images or video recordings of Plaintiff, as well as compensatory and exemplary damages.

COUNT II – VIOLATION OF NEW YORK CIVIL RIGHTS LAW §§ 52-B (UNLAWFUL DISSEMINATION OR PUBLICATION OF AN INTIMATE IMAGE) (AGAINST DR. SHRIDHARANI AND LUXURGERY)

- 82. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 83. Plaintiff brings this Count II against Dr. Shridharani and Luxurgery.
- 84. Section 52-B(1) of New York Civil Rights Law prohibits the publication of any still or video image of a person depicting such person's "unclothed or exposed intimate part" of such person for the purpose of harassment or annoyance.
- 85. As described above, Dr. Shridharani and Luxurgery made a video recording of Plaintiff's breast augmentation surgery without her consent.

- 86. The video was not made within lawful and common practices of medical treatment.
- 87. The video recording, which displayed her naked body and identifying marks, was posted by Dr. Shridharani and Luxurgery on social media, including but not limited to Instagram and TikTok, for marketing purposes without Plaintiff's written consent in March 2023.
- 88. After Plaintiff complained to Dr. Shridharani and Luxurgery, they removed the video but then posted it, or excerpts of it, on two additional occasions in 2023 and 2024.
- 89. Defendants' postings of the video on the second two occasions were done knowing Plaintiff did not consent and knowing Plaintiff strenuously objected the first time, and thus were not posted for a legitimate business purpose but instead to harass or annoy Plaintiff.
- As a result of Defendants' conduct described herein, Plaintiff has and will continue to suffer personal psychological injuries, including but not limited to great pain of mind and body; severe and permanent emotional distress; physical manifestations of emotional distress; feelings of worthlessness, shamefulness, and embarrassment; losing faith in authority figures; struggling with gainful employment and career advancement; feeling helpless and hopeless; problems with sexual intimacy; relationship problems; trust issues; feeling confused and angry; depression; and anxiety. Plaintiff was prevented from and will continue to be prevented from performing Plaintiff's normal daily activities; has incurred and will continue to incur expenses for psychological treatment, therapy, and counseling; and, on information and belief, has incurred and will continue to incur loss of income and/or loss of earning capacity.
- 91. Section 52-B(1) of New York Civil Rights Law provides that Plaintiff may seek injunctive relief as well as punitive damages, compensatory damages, and reasonable court costs and attorneys' fees.
 - 92. Plaintiff seeks an injunction to restrain Defendants' use of any images or video

recordings of Plaintiff, as well as compensatory and exemplary damages.

COUNT III – VIOLATION OF NEW YORK CIVIL PRACTICE LAW § 4504 (PHYSICIAN-PATIENT CONFIDENTIALITY) (AGAINST DR. SHRIDHARANI AND LUXURGERY)

- 93. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 94. Plaintiff brings this Count III against Dr. Shridharani and Luxurgery.
 - 95. Section 4504(a) provides in pertinent part:

Confidential information privileged. Unless the patient waives the privilege, a person authorized to practice medicine...shall not be allowed to disclose any information which he acquired in attending a patient in a professional capacity, and which was necessary to enable him to act in that capacity. The relationship of a physician and patient shall exist between a medical corporation, as defined in article forty-four of the public health law, a professional service corporation organized under article fifteen of the business corporation law to practice medicine, a university faculty practice corporation organized under section fourteen hundred twelve of the not-for-profit corporation law to practice medicine or dentistry, and the patients to whom they respectively render professional medical services. *** For purposes of this subdivision: 1. "person" shall mean any individual, insurer or agent thereof, peer review committee, public or private corporation, political subdivision, government agency, department or bureau of the state, municipality, industry, co-partnership, association, firm, trust, estate or any other legal entity whatsoever;

NY CPLR § 4504.

- 96. Pursuant to NY CPLR § 4504, Plaintiff had a physician-patient relationship with Dr. Shridharani.
- 97. Pursuant to NY CPLR § 4504, Dr. Shridharani was not "allowed to disclose any information which he acquired in attending a patient in a professional capacity, and which was necessary to enable him to act in that capacity," including but not limited to video recordings of Plaintiff's surgery.

- 98. Pursuant to NY CPLR § 4504, Plaintiff had a physician-patient relationship with Luxurgery.
- 99. Pursuant to NY CPLR § 4504, Luxurgery was not "allowed to disclose any information which [it] acquired in attending a patient in a professional capacity, and which was necessary to enable [it] to act in that capacity," including but not limited to video recordings of Plaintiff's surgery.
- 100. Notwithstanding, Dr. Shridharani and Luxurgery made a video recording of Plaintiff's breast augmentation surgery without her written consent.
- 101. The video recording displayed Plaintiff's naked body and identifying marks, and thus was highly confidential.
- 102. Dr. Shridharani and Luxurgery posted the video on social media, including but not limited to Instagram and TikTok, for marketing purposes without Plaintiff's written consent and over her objections on at least three separate occasions.
- 103. As a result of Defendants' conduct described herein, Plaintiff has and will continue to suffer personal psychological injuries, including but not limited to great pain of mind and body; severe and permanent emotional distress; physical manifestations of emotional distress; feelings of worthlessness, shamefulness, and embarrassment; losing faith in authority figures; struggling with gainful employment and career advancement; feeling helpless and hopeless; problems with sexual intimacy; relationship problems; trust issues; feeling confused and angry; depression; and anxiety. Plaintiff was prevented from and will continue to be prevented from performing Plaintiff's normal daily activities; has incurred and will continue to incur expenses for psychological treatment, therapy, and counseling; and, on information and belief, has incurred and will continue to incur loss of income and/or loss of earning capacity.

104. Plaintiff seeks an injunction to restrain Defendants' use of any images or video recordings of Plaintiff, as well as compensatory and exemplary damages.

COUNT IV - NEGLIGENT HIRING, SUPERVISION, RETENTION, AND/OR DIRECTION (AGAINST LUXURGERY)

- 105. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 106. Plaintiff brings this Count IV against Luxurgery.
- 107. At all times herein, on information and belief, Luxurgery employed Dr. Shridharani.
- 108. Luxurgery retained Dr. Shridharani as a plastic surgeon to conduct surgeries on intimate body parts requiring the utmost confidentiality and discretion, including breast augmentation surgery.
- 109. Luxurgery was negligent in hiring, employing, and/or retaining Dr. Shridharani because Defendant knew or should have known, through the exercise of reasonable care, of Dr. Shridharani's recording of surgeries, or the approval of recording of surgeries, performed by him and the subsequent use of those intimate video recordings of patients without full and written informed consent.
- 110. Dr. Shridharani would not and could not have been in a position to video record Plaintiff's breast augmentation surgery and post or approve the posting of the video of her surgery had Dr. Shridharani not been hired or retained by Luxurgery to practice medicine.
- 111. Moreover, after the video was posted the first time, Luxurgery was on notice of Plaintiff's objections, and nonetheless allowed the video to be posted a second and third time.
 - 112. Thus, despite Plaintiff's written Informed Consent form, which did not permit the

use of images for marketing purposes, Plaintiff's oral inquiries to confirm any images could not be published publicly, and Plaintiff's strenuous objections to the initial posting of the video, Luxurgery did not take any steps or took inadequate steps to ensure that the video was not used to promote Dr. Shridharani's practice.

- 113. Luxurgery thus was negligent in its duty to supervise or provide direction to Dr. Shridharani about (i) video recording without consent; and (ii) using videos for marketing purposes without consent.
 - 114. The harm complained of was foreseeable.
- 115. Plaintiff would not have suffered the foreseeable harm complained of herein but for the negligence of Luxurgery in having hired Dr. Shridharani and allowing Dr. Shridharani to remain in his position.
- 116. At all times while Dr. Shridharani was employed or appointed by Defendants, he was supervised by Luxurgery herein or Luxurgery's agents and employees.
- 117. At all times while Dr. Shridharani was employed or appointed by Defendants, he was under the direction of Luxurgery herein or Luxurgery's agents and employees.
- 118. Luxurgery was negligent in its direction and supervision of Dr. Shridharani in that they knew or should have known, through the exercise of ordinary care, that Dr. Shridharani's conduct, including his propensity to record video, or approve the recording of video, of his surgeries without patient consent and using those videos for marketing purposes, would subject third parties to an unreasonable risk of harm.
 - 119. Luxurgery failed to take steps to prevent such conduct from occurring.
- 120. Luxurgery failed to take reasonable steps to prevent such events from occurring on Luxurgery's premises.

- 121. Luxurgery breached its duty of care to Plaintiff and was otherwise negligent.
- 122. As a direct or indirect result of said conduct or negligence, Plaintiff has suffered the injuries and damages described herein.
- 123. By reason of the foregoing, Luxurgery is liable to Plaintiff for compensatory damages, and for punitive damages, together with interest and costs.

COUNT V - NEGLIGENT HIRING, SUPERVISION, RETENTION, AND/OR DIRECTION (AGAINST LUXURGERY)

- 124. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 125. Plaintiff brings this Count V against Luxurgery.
- 126. At all times herein, on information and belief, Luxurgery employed one or more John Does as staff with responsibility for marketing and promoting Luxurgery and Dr. Shridharani.
- 127. Luxurgery retained John Does to promote Dr. Shridharani's work as a plastic surgeon who conducts surgeries on intimate body parts requiring the utmost confidentiality and discretion, including breast augmentation surgery.
- 128. Luxurgery retained John Does to promote Luxurgery as the medical center where surgeries on intimate body parts requiring the utmost confidentiality and discretion, including breast augmentation surgery, would take place.
- 129. Luxurgery was negligent in hiring, employing, training, supervising, and retaining John Does because Luxurgery knew or should have known, through the exercise of reasonable care, of John Does' recording of surgeries and the subsequent use of those intimate video recordings of patients for marketing purposes without full and written informed consent.
 - 130. John Does would not and could not have been in a position to video record

Plaintiff's breast augmentation surgery and post or approve the posting of the video of her surgery had John Does not been hired or retained by Luxurgery.

- 131. Moreover, after the video was posted the first time, Luxurgery was on notice of Plaintiff's objections, and nonetheless allowed the video to be posted a second and third time by or with the approval of John Does.
- Thus, despite Plaintiff's written Informed Consent form, which did not permit the use of images for marketing purposes, Plaintiff's oral inquiries to confirm any images could not be published publicly, and Plaintiff's strenuous objections to the initial posting of the video, Luxurgery did not take any steps or took inadequate steps to ensure that the video was not used by John Does to promote it or Dr. Shridharani's practice.
- 133. Luxurgery thus was negligent in its duty to supervise or provide direction to John Does about (i) video recording without consent; and (ii) using videos for marketing purposes without consent.
 - 134. The harm complained of was foreseeable.
- 135. Plaintiff would not have suffered the foreseeable harm complained of herein but for the negligence of Luxurgery in having hired John Does and allowing John Does to remain in their positions.
- 136. At all times while John Does were employed or appointed by Defendants, they were supervised by Luxurgery herein or Luxurgery's agents and employees.
- 137. At all times while John Does were employed or appointed by Defendants, they were under the direction of Luxurgery herein or Luxurgery's agents and employees.
- 138. Luxurgery was negligent in its direction and supervision of John Does in that Luxurgery knew or should have known, through the exercise of ordinary care, that John Does'

conduct, including their propensity to record video, or approve the recording of video, of surgeries without patient consent and using those videos for marketing purposes, would subject third parties to an unreasonable risk of harm.

- 139. Luxurgery failed to take steps to prevent such conduct from occurring.
- 140. Luxurgery failed to take reasonable steps to prevent such events from occurring on Luxurgery's premises.
 - 141. Luxurgery breached its duty of care to Plaintiff and was otherwise negligent.
- 142. As a direct or indirect result of said conduct or negligence, Plaintiff has suffered the injuries and damages described herein.
- 143. By reason of the foregoing, Luxurgery is liable to Plaintiff for compensatory damages, and for punitive damages, together with interest and costs.

COUNT VI - NEGLIGENT SUPERVISION AND/OR DIRECTION (AGAINST SIENTRA)

- 144. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 145. Plaintiff brings this Count VI against Sientra.
- 146. Sientra is the Study Sponsor of the "Prospective Study on Fat Retention when using the AuraGen 1-2-3TM with AuraClensTM System in Processing of Lipoaspirate for Autologous Fat Grafting to the Breast."
 - 147. Sientra appointed Dr. Shridharani as the Principal Investigator on the Study.
- 148. Under 21 C.F.R. § 812.40, Study Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, and for ensuring proper monitoring of the investigation.

- 149. Study sponsors are also responsible for securing an agreement from the investigator that includes a "statement of the investigator's commitment to: *** (iii) Ensure that the requirements for obtaining informed consent are met." 21 C.F.R. § 812.43.
 - 150. On information and belief, Sientra obtained this agreement from Dr. Shridharani.
- 151. On information and belief, the Informed Consent Form reflects the agreement between Sientra and Dr. Shridharani as to how informed consent would be obtained from patients.
- 152. Dr. Shridharani did use the Informed Consent Form with Plaintiff, and Plaintiff signed the Informed Consent Form.
- 153. The Informed Consent Form provides that photographs and 3D imaging might be taken of her breasts for dimensional measurement, that reasonable measures would be taken to ensure that identifying information would not be included in any photographs, and that the photographs would only be shared with the Investigator, study site personnel, study sponsor, and sponsor authorized representatives for research purposes.
- 154. In the Informed Consent Form, Jane Doe expressly withheld consent to the use of any photographs for marketing purposes.
- 155. The Informed Consent Form did not disclose that any video recordings of her would be taken while she was unconscious during surgery.
- 156. Notwithstanding, Dr. Shridharani arranged for or approved the video recording of Plaintiff's surgery, and arranged for or approved the use of such video for marketing purposes.
- 157. Under 21 C.F.R. § 812.46, "[a] sponsor who discovers that an investigator is not complying with the signed agreement...shall promptly... secure compliance,...."
- 158. On or about June 16, 2023, after Dr. Shridharani and Luxurgery posted the video on social media for the second time, Jane Doe sent an email to the Study Subject Advisor, Advarra,

seeking action to ensure that the posting of the videos depicting her intimate body parts on social media would not occur again.

- 159. On information and belief, Advarra did or should have notified Sientra of the complaint and its investigation into Dr. Shridharani's failure to obtained written consent to record a video of the surgery or to use the recording (or any images) for marketing purposes.
- 160. Notwithstanding the fact that Sientra knew or should have known, Sientra failed to promptly secure compliance. As a result, Dr. Shridharani posted, or approved the posting, of the video of Plaintiff's surgery a third time on social media.
- 161. As a direct or indirect result of said conduct or negligence, Plaintiff has suffered the injuries and damages described herein.
- By reason of the foregoing, Defendant Sientra is liable to Plaintiff for compensatory damages, and for punitive damages, together with interest and costs.

COUNT VII - NEGLIGENT SUPERVISION AND/OR DIRECTION (AGAINST ADVARRA)

- 163. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 164. Plaintiff brings this Count VII against Advarra.
- 165. Sientra is the Study Sponsor of the "Prospective Study on Fat Retention when using the AuraGen 1-2-3TM with AuraClensTM System in Processing of Lipoaspirate for Autologous Fat Grafting to the Breast."
- 166. Sientra retained Advarra as the Study Subject Adviser and institutional review board for the Study. According to the Informed Consent Form, "[a]n institutional review board (IRB) is an independent committee established to help protect the rights of research subjects."

- 167. According to the Federal Food and Drug Administration (FDA), "[t]he purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research."
- 168. In regards to the IRB's role with respect to informed consent by study participants, the FDA explains:

The fundamental purpose of IRB review of informed consent is to assure that the rights and welfare of subjects are protected. A signed informed consent document is evidence that the document has been provided to a prospective subject (and presumably, explained) and that the subject has agreed to participate in the research. IRB review of informed consent documents also ensures that the institution has complied with applicable regulations.⁷

- 169. Here, the Informed Consent Form for the Study provided that photographs and 3D imaging might be taken of Plaintiff's breasts for dimensional measurement, that reasonable measures would be taken to ensure that identifying information would not be included in any photographs, and that the photographs would only be shared with the Investigator, study site personnel, study sponsor, and sponsor authorized representatives for research purposes.
- 170. In the Informed Consent Form, Jane Doe expressly withheld consent to the use of any photographs for marketing purposes.
- 171. The Informed Consent Form did not disclose that any video recordings of her would be taken while she was unconscious during surgery.
- 172. Notwithstanding, Dr. Shridharani arranged for or approved the video recording of Plaintiff's surgery, and arranged for or approved the use of such video for marketing purposes

⁶ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions (last accessed Jan. 28, 2024).

⁷ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions (last accessed Jan. 28, 2024).

without Plaintiff's consent.

- 173. On June 16, 2023, Jane Doe saw the video of her unclothed body, including her breast and areola, taken during her surgery on social media for the second time. The video had been posted by Dr. Shridharani and Luxurgery on TikTok and Instagram on June 14, 2023.
- 174. Just as the first time, the video clearly depicts identifying marks on Jane Doe's body, including a tattoo.
- 175. On June 16, 2023, Jane Doe sent an email to the Study Subject Advisor, Advarra, seeking action to ensure that the posting of the videos depicting her intimate body parts on social media would not occur again.
- 176. Jane Doe expected that Advarra would help protect her given that its job was to ensure that the rights of study participants were not violated.

177. Jane Doe wrote to Advarra:

I had recently agreed to be a participant in the Study Reference: Pro00061014 and I am reporting a violation in the study. On March 24th 2023, I saw a video of me in this procedure that was posted by Dr. Sachin M Shridharani on social media. I immediately contacted the office and they removed it. I was shocked, however, to once again find that the video was reposted again on June 14th, 2023 once again without my consent. The video clearly shows my tattoo as well as my areola in plain view. The contract clearly states that all identifying features and marks will be removed and my own marks were clearly not removed on these videos as well as my nude body.

The Investigator medical doctor clearly has broken the contract and I have been harmed both psychologically and emotionally and feel violated and abused by the Investigator. I am demoralized and cannot believe that such an occurrence would happen involving medical research. This has triggered me to the point where I have been feeling suicidal- as I am already in therapy for prior sexual abuse. I am enclosing a letter from my therapist as well. I would like this matter to be promptly addressed. I only consented to a scientific study and not to any marketing wherein my personal

marks and identifiers as well as my areola are clearly visible. The Investigator misled me and had reassured me that my images/video would NOT be used for marketing purposes. To this point, the investigator has clearly harmed me for his own financial gain and profit.

- 178. While Advarra confirmed receipt of the email, it largely ignored Jane Doe. For the next two months, Jane Doe regularly followed up by email with Advarra to find out how it intended to protect her rights.
- 179. After two months, on August 16, 2023, Advarra simply responded: "After review, the Board has determined that the site will be required to revise the consent form and change their processes in regard to collecting photographs, videos, and/or audio recordings of patients."
- 180. Advarra was silent as to how Jane Doe would be protected from the use of pictures and video of her being used by Dr. Shridharani and Luxurgery for marketing purposes.
- 181. Jane Doe was very upset by Advarra's response and its failure to help protect her and wrote to Advarra about its failure to protect her.
- 182. Advarra was negligent in its failure to cause Dr. Shridharani and Luxurgery to take steps to prevent the posting of the video of Plaintiff's surgery without her consent or to ensure that any videos or pictures were segregated and held in confidence in accordance with the terms of the Informed Consent Form.
- 183. As a result, on January 10, 2024, for the third time, Dr. Shridharani and Luxurgery posted a video on Instagram and TikTok which is comprised of multiple videos of multiple women, including a segment of the video of Jane Doe's surgery.
- 184. Jane Doe saw this video on January 12, 2024, causing her extreme emotional distress.
 - 185. As a direct or indirect result of said conduct or negligence, Plaintiff has suffered

the injuries and damages described herein.

186. By reason of the foregoing, Defendant Advarra is liable to Plaintiff for compensatory damages, and for punitive damages, together with interest and costs.

COUNT VIII: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS (AGAINST ALL DEFENDANTS)

- 187. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 188. This Count VIII is asserted against all Defendants.
- 189. Defendants' extreme and outrageous conduct intentionally or recklessly caused severe emotional distress to Plaintiff.
- 190. Defendants' outrageous conduct was not the type of ordinary rude or obnoxious behavior that patients should be expected to weather. Rather, Defendants' conduct exceeded all possible bounds of decency.
- 191. Defendants acted with intent or recklessness, and knew or should have known that Plaintiff was likely to endure emotional distress.
- 192. Defendants' conduct caused suffering for Plaintiff at levels no reasonable person should have to endure.
- 193. As a direct result of Defendants' actions, Plaintiff suffered pain and suffering, mental anguish, and loss of the capacity for the enjoyment of life, and has incurred expenses for medical treatment, loss of property, loss of earnings and/or the loss of the ability to earn money. These losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.
- 194. Defendants' acts were intentional, done with malice, and/or showed a deliberate, willful, wanton, and reckless indifference to Plaintiff's rights, for which she is entitled to an award

of punitive damages.

COUNT IX: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS (AGAINST ALL DEFENDANTS)

- 195. Plaintiff repeats and realleges by reference each and every allegation set forth above as if fully set forth herein.
 - 196. This Count IX is asserted against all Defendants.
- 197. Defendants owed Plaintiff a duty of care to maintain the confidentiality of her information and images in accordance with the Informed Consent Form.
- 198. The duty of care owed by Dr. Shridharani and Luxurgery arises out of the physician-patient relationship and duty of confidentiality.
- 199. The duty of care owed by Sientra arises out of its role as the Sponsor of the Study and Jane Doe's role as a Study participant. Sientra was responsible for ensuring that the Principal Investigator acted in accordance with the Study Informed Consent Form in order to protect the rights of study participants like Jane Doe. Sientra was also responsible for ensuring that it took action to protect the rights of study participants when substantiated complaints, like Jane Doe's, were brought to the attention of the IRB.
- 200. The duty of care owed by Advarra arises out of its role as the IRB and its duty to protect the rights of study participants like Jane Doe.
 - 201. Defendants' conduct negligently caused severe emotional distress to Plaintiff.
- As a direct result of Defendants' actions, Plaintiff suffered pain and suffering, mental anguish, and loss of the capacity for the enjoyment of life, and has incurred expenses for medical treatment, loss of property, loss of earnings and/or the loss of the ability to earn money. These losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

Plaintiff's psychological traumas are readily and unquestionably understandable given the

repeated postings to social media, and lack of clarity despite her repeated objections as to whether

additional copies of the videos (or excerpts thereof) exist, who may be in possession of the videos,

where they may be posted, and whether they will be posted in the future on any number of Internet

sites.

WHEREFORE, Plaintiff respectfully requests that the Court grant an injunction against

Defendants preventing the use of images or recordings of Plaintiff for any purpose, grant judgment

in this action in favor of the Plaintiff, and against Defendants, and award her compensatory

damages, damages for pain and suffering, exemplary damages, attorneys' fees and costs, and such

other and further relief as this Court deems is just, proper, and equitable.

Dated: February 8, 2024

FEGAN SCOTT LLC

By: <u>/s/ Melissa Ryan Clark</u>

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Counsel for Plaintiff

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JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff Jane Doe hereby demands a trial by jury in the above-captioned action of all issues triable by jury.

Dated: February 8, 2024 FEGAN SCOTT LLC

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